K102870

Exactech® Proliant™ Polyaxial Pedicle Screw System
Traditional 510(k)

510(k) Summary

JAN 2 1 2011

Company:	Exactech®, Inc 2320 NW 66th Court Gainesville, FL 32653
Date:	November 22, 2010
Contact Person:	Vladislava Zaitseva Regulatory Affairs Specialist Phone: 508-377-1140 Fax: (352) 378-2617
Proprietary Name:	Exactech® Proliant™ Polyaxial Pedicle Screw System
Common Name:	Pedicle screw spinal system

Classification Name:
21 CFR 888.3070 - Pedicle screw spinal system, Class II

- Product Code: MNI - Orthosis, Spinal Pedicle Fixation
- Product Code: MNH - Orthosis, Spondylolisthesis Spinal Fixation

Legally Marketed Devices to Which Substantial Equivalence Is Claimed

- Hydralok™ System (K051216)
- VSS System (K062670) and Extended VSS System (K073245)

Device Description
This submission proposes a new pedicle screw spinal fixation system. The proposed Proliant Polyaxial Pedicle Screw System is a top-loading spinal fixation system that comprises various sizes of polyaxial screws, rigid rods and cross connectors to provide immobilization and stabilization of spinal segments as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine including degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor and failed previous fusion (pseudoarthrosis).

Components are manufactured from titanium alloy (Ti-6AI-4V ELI per ASTM F136). The system components are provided clean and non-sterile. The products must be steam sterilized by the hospital prior to use.

The Proliant Polyaxial Pedicle Screw System includes a complete instrumentation system to assist the surgeon in the implantation of each component according to a traditional open surgical procedure.

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Indications for Use
The Exactech® Proliant™ Polyaxial Pedicle Screw System is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine including degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor and failed previous fusion (pseudoarthrosis).

In addition, when used as a pedicle screw fixation system, the Exactech Proliant Polyaxial Pedicle Screw System is intended for skeletally mature patients with severe spondylolisthesis (Grades 3 and 4) of the L5-S1 vertebra, who are receiving fusion by autogenous bone graft only having the device attached to the lumbar and sacral spine (L3 and below), who are having the device removed after the development of a solid fusion.

Summary of Technological Characteristics
The rationale for substantial equivalence is based on consideration of the following characteristics:

- **Intended Use/Indications for Use.**
  The Proliant Polyaxial Pedicle Screw System has the same indications for use and intended uses as the Hydralok System and similar indications for use and intended uses as VSS/Extended VSS Systems.

- **Materials**
  The Proliant Polyaxial Pedicle Screw System and predicates Hydralok System and VSS/Extended VSS Systems are composed of titanium, a biocompatible material conforming to a recognized industry standard for permanent implants.

- **Design Features**
  The Proliant Polyaxial Pedicle Screw System and predicates Hydralok System and VSS/Extended VSS Systems have similar design features.

- **Dimensions**
  The Proliant Polyaxial Pedicle Screw System and predicates Hydralok System and VSS/Extended VSS Systems are dimensionally comparable.

- **Packaging and Sterilization**
  The Proliant Polyaxial Pedicle Screw System and predicates Hydralok System and VSS/Extended VSS Systems are provided non-sterile for single use only. Both proposed and predicate systems will be steam sterilized by the hospital prior to use in the operating room using the same method.

- **Device Shelf Life**
  Neither the Proliant Polyaxial Pedicle Screw System nor identified predicates have shelf-life expiration dating.

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- **Performance specifications**
  The Proliant Polyaxial Pedicle Screw System and predicate systems withstand clinically relevant biomechanical loads.

Substantial Equivalence Conclusion
The following mechanical testing and engineering analysis were conducted to demonstrate substantial equivalence of the proposed Proliant Polyaxial Pedicle Screw System to predicates Hydralok System and VSS/Extended VSS Systems:

- Static Compression Bending, Static Torsion, and Dynamic Compression Fatigue testing per ASTM F1717.

- Biomechanical assessment comparing Proliant Polyaxial Pedicle Screw System mechanical performance to cited predicate systems.

The results of mechanical testing and engineering analysis demonstrate the proposed devices are substantially equivalent to cited predicates.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Exactech®, Inc.
% Ms. Vladislava Zaitseva
Regulatory Affairs Specialist
2320 NW 66th Court
Gainesville, Florida 32653

JAN 2 1 2011

Re: K102870
Trade/Device Name: Exactech® Proliant™ Polyaxial Pedicle Screw System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class II
Product Code: MNI, MNH
Dated: December 22, 2010
Received: December 23, 2010

Dear Ms. Zaitseva:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Exactech® Proliant™ Polyaxial Pedicle Screw System
Traditional 510(k)

Indications for Use Statement

510(k) Number: K102870

Device Name: Exactech® Proliant™ Polyaxial Pedicle Screw System

INDICATIONS FOR USE:
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Prescription Use __X__ **and/or** **Over-The-Counter Use** _____
(Part 21 CFR 801 Subpart D) **(21 CFR 807 Subpart C)**

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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